REMARKS

Claims 9-20 have been deleted without prejudice to filing a divisional or continuation application. Claims 1 to 8 have been amended to address transdermal drug delivery devices. The amendment is supported by the specification, for example, in the originally filed claims and the drawings. No new matter is added. New claims 21-22 have been added to address the selection of pH in relation to the ionic nature of the reservoir. The new claims are supported by the specification, for example, on page 14, lines 1-11. No new matter is added. New claims 23-24 are added to address transdermal drug delivery devices with reservoirs. The new claims are supported by the specification, for example, in the originally filed claims and the drawings. No new matter is added. New claims 25-34 are added to address a method of making transdermal drug delivery devices. The new claims are supported by the specification, for example, the original claims and drawing and on page 14, lines 1-11. No new matter is added. Claims 1-8 and 21-34 are pending.

Election/Restriction

The Examiner has required a restriction and asked Applicants to cancel unelected claims 9-20. Applicants have canceled claims 9 to 20. However, Applicants have amended claims 1-8 to address the species of a transdermal delivery apparatus, which was originally covered by claims 9-11.

Rejection Under § 112

The Examiner has rejected claims 1-8 as being indefinite for failure to particularly point out and distinctly claim the subject matter which Applicants regard as the invention because the claims refer to "dipeptide buffer". The Examiner asserts that the claim is confusing as to how a dipeptide can contain 3-5 amino acids and still be a dipeptide. Applicants have deleted the "dipeptide" term from the claims. Withdrawal of the rejection is respectfully requested.

Rejection under 35 USC § 102(b) or § 103(a) over Sorensen

The Examiner has rejected claims 1-8 under 35 U.S.C. § 102(b) as being anticipated or in the alternative being prima facie obvious over Sorensen WO 93/12812 (7/93).

It is submitted that Sorensen is entirely unrelated to transdermal drug delivery. There is nothing in the Sorensen document that will give guidance to a person skilled in the art on the property of an electrotransport reservoir for drug delivery. Further, although Sorensen might have given some examples of a formulation with a pH within 1 unit of the pI of dipeptide in the formulation, there are also other formulations with a pH not within 1 unit of the pI of dipeptide in the formulation and with pKa not the same as what is presently being claimed, among other differences. There is no teaching or suggestion by Sorensen to choose one over the other. Just because something narrower is present among a broader range of choices does not mean one would be motivated to choose a particular narrower choice. It is noted that Applicants have discovered that the pH and ionic properties of the reservoir render the peptidic buffer with peptide of particular pI's especially suitable for maintaining pH in the reservoir for long period of time to minimize skin irritation in electrotransport drug delivery. This relationship and combination of the properties of the polypeptides and the reservoir is one of the aspects of the novelty and nonobviousness of the present invention.

Applicants respectfully request the withdrawal of the § 102(b) and § 103(a) rejections.

Rejection under 35 USC § 103(a) over Bjorn

The Examiner has rejected claims 1-8 as being obvious over Sorensen, WO 97/39768.

It is noted that Bjorn does not teach having a polypeptide at a pH within 1 unit of the pI of the polypeptide. The Examiner asserted that in Example 1 at page 18 Bjorn shows such an embodiment. However, as the Examiner stated, the preparation in Example 1 contains L-His, which is not a polypeptide, and therefore does not fit the claimed element. Just because Bjorn writes about different dipeptides (which may have different pI's) does not mean Bjorn gives any guidance on selection of pH to be within 1 unit of the pI of a polypeptide. Although Bjorn mentions a pH range of 6 to 8.8, there is no indication of choosing within that broad range a pH of within 1 unit of a pI of a polypeptide. The Examiner asserts that optimization of pH and concentration in order to obtain optimum buffering capacity is within on skilled in the art. However, Applicants have discovered that the pH and ionic properties of the reservoir renders

the peptidic buffer with particular pI and pKa's particularly suitable for maintaining pH in the reservoir for electrotransport drug delivery. This relationship is entirely unrelated to and not mentioned by Bjorn. Similar to the absence of motivation discussed in the above related to Sorensen, there is also no motivation to select the particular narrow ranges of pKa, pI, pH, in relation to the electrotransport reservoir based on Bjorn. For an obviousness rejection, there must be some motivation or suggestion to modify a reference. Since Bjorn does not mention any need to keep pH within 1 unit of pI of a polypeptide, or the selection of particular pKa's, and their technology is entirely unrelated to electrotransport, there is no such motivation.

Applicants respectfully request the withdrawal of the § 102(b) and § 103(a) rejections.

CONCLUSION

Applicants submit the pending claims are novel and nonobvious over prior art and comply with the requirements of 35 USC 112. The examination and passage to allowance of the pending claims are respectfully requested. An early Notice of Allowance is therefore earnestly solicited.

Applicant invites the Examiner to contact the undersigned at (650) 564-7054 to clarify any unresolved issues raised by this response.

Respectfully submitted,

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